



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,862	12/10/1999	ALLISON HUBEL	600.451US1	9374

21186 7590 12/23/2002

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER

PESELEV, ELLI

ART UNIT	PAPER NUMBER
----------	--------------

1623

DATE MAILED: 12/23/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/458,862

Applicant(s)

HUBEL, ALLISON

Examiner

Elli Peselev

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11, 12, 14, 16, 17, 19-22, 24, 26-28, 30-44 and 47-58 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11, 12, 14, 16, 17, 19-22, 24, 26-28, 30-44 and 47-58 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claims 1-8, 11-12, 14, 16-17, 19-22, 24, 26-28, 30-44 and 47-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for arabinogalactan, does not reasonably provide enablement for a biological or functional equivalent thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification fails to provide enablement for the biological or functional equivalents of arabinogalactan and it would take an undue amount of experimentation to determine which specific biological or functional equivalents of arabinogalactan would be useful in the claimed compositions and methods.

Claims 1-8, 11-12, 14, 16-17, 19-22, 24, 26-28, 30-44 and 47-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what is encompassed by the terminology "a biological or functional equivalent thereof". The disclosure on page 9 of the specification stating that arabinogalactan derivatives described in U.S. Patents Nos. 5,478,576 and 5,116,969 are included within the scope of the terminology "arabinogalactan, and biological and functional equivalents thereof" has been noted. However, the terminology "biological or functional equivalents thereof" is not limited to the prior art disclosure and it cannot be ascertained what additional compounds are encompassed by said terminology.

It is not clear from the specification how lymphocytes are modified ex vivo. The specification fails to present any examples of such modification.

Claims 1-8, 11-12, 14, 16-17, 19-22, 24, 26-28, 30-44 and 47-58 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over PCT Patent No. WO 97/35472 for the reasons set forth in the Office Action of October 25, 2000.

Applicant's arguments filed December 4, 2002 have been fully considered but they are not persuasive.

The PCT Patent discloses that arabinogalactan is not toxic to cells and is highly compatible with a wide variety of different cell types (page 9, lines 20-24), including blood cells (page 10, line 4). The PCT Patent also discloses that cells may be frozen in arabinogalactan alone and teaches the use of DMSO as optional (page 9, lines 12-15). The prior art disclosure is applicable for everything it discloses and is not limited to specific examples set forth therein. Further, the terminology "high post-thaw survival rate" encompasses a wide range of rates since it is not limited by any specific number.

The data presented in the PCT Patent encompasses medium containing 50% of AG, 20% AG, 15% AG and 10% AG. The PCT Patent discloses that medium containing 50% AG can be used to replace serum but a lower percentage of AG was not successful. However, note that lower percentages of AG disclosed are 20%, 15% and 10% while the instant claims encompass 40% of AG. Since 40% is closer to 50% than to 20%, a person having ordinary skill in the art at the time the instant invention was

Art Unit: 1623

made would have expected that compositions containing 40% AG would produce results which are more similar to those produced by a composition containing 50% AG.


The declarations by Dr. Hubel and Dr. Bischof and prior art have been considered but havenot been found persuasive since PCT Patent discloses cryopreservation of a wide variety of cell types, including blood cells and since the rejection over the prior art does not require 100% predictability.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is 703-308-4616. The examiner can normally be reached on weekdays 8.30 a.m. - 5.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Elli Peselev
December 19, 2002


ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200